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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/024,988  | 02/17/1998  | RANDALL W. NELSON    | 5015C1              | 9007             |
| 20322   | 7590        | 06/07/2005           | EXAMINER            |                  |
| SNELL & WILMER<br>ONE ARIZONA CENTER<br>400 EAST VAN BUREN<br>PHOENIX, AZ 850040001 |             |                      |                     | HOLLERAN, ANNE L |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1642                |                  |

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/024,988             | NELSON ET AL.       |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Anne Holleran          | 1642                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 07 March 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 31-40 and 42-50 is/are pending in the application.
  - 4a) Of the above claim(s) 32,34-39 and 42-47 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 31, 33, 40 and 48-50 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

|   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br/>         Paper No(s)/Mail Date _____.</li> </ol> | <ol style="list-style-type: none"> <li>4)<input type="checkbox"/> Interview Summary (PTO-413)<br/>         Paper No(s)/Mail Date. _____.</li> <li>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6)<input type="checkbox"/> Other: _____.</li> </ol> |
|---|---|

**DETAILED ACTION**

1. Applicants' amendment filed March 7, 2005 is acknowledged. Claims 31-40 and 42-50 are pending. Claims 32, 34-39 and 42-47, drawn to non-elected inventions, are withdrawn from consideration.

Claims 31, 33, 40 and 48-50 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The declaration of Allan L. Bieber, filed 6/18/2004, has been considered.

***Claim Rejections Withdrawn:***

4. The rejection of claims 31, 33, 40 and 48-50 under 35 U.S.C. 102(a) as being anticipated by Nelson (Nelson, R.W. et al, Anal. Chem. 67: 1153-1158, 1995, April 1) is withdrawn in view of the declaration by Allan L. Bieber. In the declaration, it was stated that co-author Allan L. Bieber did not contribute to the conception of the subject matter disclosed in the Nelson. Therefore, the inventive entity of Nelson is now the same as the inventive entity of the instant application, and Nelson is not available as prior art under 102(a).

***Claim Rejections Maintained and New Grounds of Rejection:***

5. Claims 31, 33, 40 and 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 31 and 48 contain the phrase (added by amendment) “wherein analyzing and quantifying comprises using only mass spectrometric analysis to resolve distinct signals ...”. The problem arises because of the juxtaposition of the transitional phrase “comprising” with the phrase “using *only* mass spectrometric analysis”. It appears that applicant is intending to limit the scope of step “c”. However, coupling a broad and inclusive term such as “comprising” with a narrow term such as “only” causes confusion, and the scope of claim is called into question. Dependent claims 33 and 40 (for claim 31) and dependent claims 49 and 50 (for claim 48) further add to the confusion, because these claims add an element to the quantification step, which has been characterized in the independent claims as “using *only* mass spectrometric analysis...”. Therefore, the claims are indefinite. This issue may be resolved by amending claims 31 and 48 to recite: “wherein analyzing and quantifying comprises using matrix-assisted laser desorption/ionization (MALDI) to resolve distinct signals for said analyte and said IRS to determine the ratio of the analyte signal to the IRS signal.”

6. Claims 31, 33 and 40 remain rejected under 35 U.S.C. 102(b) as being anticipated by Gaskell and Brownsey (Clin. Chem., 29(4): 677-680, 1983), Gaskell (Steroids, 55: 458-462, 1990), Bonfanti (Cancer Research, 50: 6870-6875, 1990) or Davoli (Anal. Chem., 65: 2679-2685, 1993) for the reasons of record.

Applicants' arguments have been considered but are unpersuasive. Applicants continue to argue that each of the references fails to teach the claimed inventions, because the methods taught in the references require steps not recited in the claims. However, the claimed invention reads on methods that contain other purification steps, or contain a derivatization step, because the claimed methods are drawn to a method "comprising" the steps recited in the claims.

Applicants have attempted to obviate the rejection by amending claim 31 to recite "using only mass spectrometric analysis". However, this amendment fails to obviate the rejections because, as explained above, the amendment to the claims renders the claims indefinite. Because the phrase "comprises using only mass spectrometric analysis" is unclear, and further because claim 31 contains the phrase "said method comprising the steps of", steps other than the ones specifically recited may be included in methods encompassed by the claims. Additionally, the phrase "only mass spectrometric analysis" does not preclude a preliminary purification step or preparation step. As indicated above, this issue may be resolved by amending claim 31 to recite: "wherein analyzing and quantifying comprises using matrix-assisted laser desorption/ionization (MALDI) to resolve distinct signals for said analyte and said IRS to determine the ratio of the analyte signal to the IRS signal."

7. Claims 31, 33, 40 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Lisek (Lisek, C.A. et al. Rapid Communications in Mass Spectrometry 3(2): 43-46, 1989;) for the reasons of record.

Applicants' arguments have been carefully considered but fail to persuade. Applicants' arguments appear to be based on the same reasoning as applied to the arguments against the

rejections based on the Gaskell and Brownsey, Gaskell, Bonfanti or Davoli references. The rejection of claims as being anticipated by Lisek is maintained because the amendments to claims 31 and 48 fail to obviate the rejections for the reasons set forth above. Also, as noted above, even if the amendment was clear, the phrase "using only mass spectrometric analysis" does not preclude the use of other steps in the claimed methods because the claims contain the phrase "said method comprising the steps of:". This issue may be resolved by amending claims 31 and 48 to recite: "wherein analyzing and quantifying comprises using matrix-assisted laser desorption/ionization (MALDI) to resolve distinct signals for said analyte and said IRS to determine the ratio of the analyte signal to the IRS signal."

***New Grounds of Rejection:***

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 31, 33, 40 and 48-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-14, 20-28, 31-33, 35-40, 42, 44, 45, 46 and 48 of copending Application No. 09/808,314, filed 3/14/2001.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4-14, 20-28, 31-33, 35-40, 42, 44, 45, 46 and 48 of copending Application No. 09/808,314 are drawn to methods for determining how much of, or the relative amount of, one or more certain antigens (or antibodies or analytes) are present in a sample, comprising the steps of adding an internal reference species to the sample, and appears to comprise a step of using mass spectrometry to quantify the signals of the antigens, antibodies or analytes together with the internal reference species. Therefore, the claims of 09/808,314 appear to be encompassed by claims 31, 33, 40, and 48-50, because these claims are drawn to methods for quantifying analytes or proteins in a sample, comprising the addition of an internal reference species and the use of mass spectrometry.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran

Patent Examiner

May 31, 2005

*Anne L. Holleran*  
ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER